

to local communities linking their health care systems, along with providing grants for purchasing health information technology.

Creating a safe, secure and reliable system for medical records won't be easy, but if done properly, it could help health care providers reduce medical errors and provide better care to their patients. We could also see a substantial savings in administrative costs which will help lower health care costs for everyone.

S. 2710 is a good first step, and I am proud to be a co-sponsor. I am hopeful that the members of the Senate Committee on Health, Education, Labor and Pensions can work together to pass this bill soon, and that we can get it to the President's desk by the end of the year.

LABOR-HHS APPROPRIATIONS

Mr. GREGG. Mr. President, the Senate will soon have the opportunity to consider the 2005 Labor-Health and Human Services Appropriations bill recently passed the House. Included in that bill is a provision that would divert \$500,000 in funding from the Office of the General Counsel at the Food and Drug Administration—FDA. As chairman of the committee with oversight over the FDA, I believe that such a provision is not only misguided, but based upon a flawed understanding of both the Agency and the facts.

According to the sponsors of this provision, such a punitive measure is warranted because the current Chief Counsel, Dan Troy, is taking the Agency "in a radical new direction" by filing amicus curiae briefs in product liability cases. Sponsors of this provision also claim that Mr. Troy's involvement in one such case is suspect because it involved Pfizer, a client of Mr. Troy's when he was with the law firm of Wiley, Rein & Fielding. Such charges are patently without merit, and I would like to take this opportunity to set the record straight.

First, Mr. Troy has not broken any new ground by having the FDA interject in product liability cases on the side of a defendants without the court requesting the Agency's position. I have here a letter addressed to me from five former FDA chief counsels—two of which are Democrats—affirming that Mr. Troy's actions are neither "radical" nor "novel." I ask unanimous consent that a copy of that letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

JULY 21, 2004.

Re Hinchey Amendment to cut \$500,000 from the appropriations for the FDA Office of Chief Counsel

Hon. JUDD GREGG,
Chairman, Health, Education, Labor and Pensions Committee, U.S. Senate, Washington, DC.

DEAR CHAIRMAN GREGG: The undersigned comprise all of the former Chief Counsel to the Food and Drug Administration (in both

Republican and Democratic Administrations), except for one who is currently an attorney in the Office of the General Counsel of the Department of Health and Human Services. We are writing to recommend reconsideration of the amendment to the FDA appropriations bill by Representative Hinchey of New York on the floor of the House of Representatives, which would reduce the appropriation for the FDA Office of Chief Counsel by \$500,000 and would increase the appropriation for the Division of Drug Marketing, Advertising, and Communications in the FDA Center for Drug Evaluation and Research by a corresponding amount. We support additional funds for the Division of Drug Marketing, but we believe that the reduction of the appropriation for the Office of Chief Counsel and Representative Hinchey's reasons for penalizing that Office cannot be supported.

FDA's Office of Chief Counsel performs critical functions in the administration and enforcement of the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA. The substantial reduction in the funding of that Office, therefore, would materially impair its ability to meet the needs of its client, FDA. Such impairment would be contrary to the public interest.

Representative Hinchey's reasons for penalizing the Office of Chief Counsel and criticizing FDA Chief Counsel Daniel E. Troy are set forth in the House Debate on the FDA appropriations legislation as reported in 150 Cong. Rec. H5598–H5599 (July 13, 2004). Representative Hinchey states that Mr. Troy "has taken the agency in a radical new direction" by submitting amicus curiae briefs in cases in which courts have been asked to require labeling for pharmaceutical products that conflicts with FDA decisions about appropriate labeling for those products. Representative Hinchey characterizes this activity as a "pattern of collusion between the FDA and the drug companies and medical device companies" in a way that has "never happened before."

These characterizations are inaccurate. In *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973), the Supreme Court agreed with the briefs filed by the Department of Justice on behalf of FDA that the agency has primary jurisdiction over new drug issues. In *Jones v. Rath Packing Co.*, 425 U.S. 933 (1977), the FDA took the position in an amicus curiae brief submitted by the Department of Justice that federal food labeling requirements preempt inconsistent state requirements, and the Supreme Court agreed. In subsequent private tort litigation, FDA has taken the position, through amicus curiae briefs filed by the Department of Justice, that FDA decisions regarding drug product labeling and related issues preempt inconsistent state court determinations, and the courts have agreed. E.g., *Bernhardt v. Pfizer, Inc.*, 2000 U.S. Dist. Lexis 16963 (November 16, 2000); *Eli Lilly & Co. v. Marshall*, 850 S.W. 2d 164 (Texas 1993). All of this was to protect a uniform national system of food and drug law. All of it occurred before Mr. Troy assumed his current position. In none of these cases did any court request FDA's opinion. Thus, there is ample precedent for the actions that Mr. Troy has recently been undertaking. His action is not radical or even novel.

The amicus curiae briefs filed by the Department of Justice at the request of Mr. Troy protect FDA's jurisdiction and the integrity of the federal regulatory process. There is a greater need for FDA intervention today because plaintiffs in courts are intruding more heavily on FDA's primary jurisdiction than ever before. In our judgment, Mr. Troy's actions are in the best interests of the consuming public and FDA. If every state

judge and jury could fashion their own labeling requirements for drugs and medical devices, there would be regulatory chaos for these two industries that are so vital to the public health, and FDA's ability to advance the public health by allocating scarce space in product labeling to the most important information would be seriously eroded. By assuring FDA's primary jurisdiction over these matters, Mr. Troy is establishing a sound policy of national decisions that promote the public health and, thus, the public interest.

We therefore recommend that the \$500,000 cut from the appropriations for the FDA Office of Chief Counsel be restored.

Sincerely yours,

PETER BARTON HUTT (1972–1975).

RICHARD A. MERRILL (1975–1977).

RICHARD M. COOPER (1977–1979).

NANCY L. BUC (1980–1981).

THOMAS SCARLETT (1981–1989).

Mr. GREGG. Mr. President, second, as stated in the letter from the five former FDA chief counsels, the FDA has been filing amicus briefs for such purposes since long before Mr. Troy's tenure. Mr. Troy is responsible for safeguarding the FDA's ability to carry out the responsibilities Congress has given the Agency, and his interest in those cases has been to preserve the FDA's authority and to safeguard the Agency's primary jurisdiction.

Finally, if Mr. Troy's previous work for a client—in this case Pfizer—automatically precluded him from representing a federal agency in any matter affecting that client, such a policy would not only discourage, but make it extremely difficult for any private sector attorney from taking a job in government. Additionally, I know from personal experience that Mr. Troy has the character and the integrity to recuse himself from a matter when appropriate. On at least one occasion in which my office was required to interact with the FDA, Mr. Troy recused himself from involvement in the matter, citing his interest in complying strictly with FDA rules.

Mr. Troy's actions are neither inappropriate nor unprecedented. Rather, these are examples of Mr. Troy doing his job and enforcing the law. I urge my colleagues to carefully consider these facts before supporting any provision, such as this one, that would undermine the FDA's ability to protect the public health and patient access to safe and effective life-saving therapies.

AVIATION SECURITY

Mr. HOLLINGS. Mr. President, the 9/11 Commission released its report today on the events leading up to 9/11, and the security failures that precipitated this tragedy. The Senate Commerce Committee has spent a great deal of its time and attention on aviation security over the years. I have served in the U.S. Senate for more than 38 years. This institution can be slow to make decisions, but when needed, this body can move quickly and effectively. After 9/11, we acted immediately